

DEC 10 1996

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12. 510(k) SUMMARY, SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21CFR 807.92:

The ACTIS® (Venous Flow Controller) device is an erection enhancement device that is designed to slow venous outflow from the penis and thus aid in the normal erection process. It is a linear elastic tube with an O ring and ball locking unit that allows ease of adjustment to increase or decrease tension. Placement is around the base of the penis.

Directions and diagrams for proper use, care, and recommended duration of application of the ACTIS® device are part of the materials provided to the patient. The ease of adjustability provides a high degree of safety when used according to the directions.

VIVUS ACTIS® device is substantially equivalent to the marketed ENCORE Revive® series of tension rings.



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Originally submitted July 25, 1996
Revised October 7, 1996